

## **REMARKS**

Applicants have carefully considered the Examiner's Final Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Pending in this Application are Claims 1, 4-6, 8-12, and 15-39. Claims 21-35 and 37-38 are withdrawn as belonging to a non-elected invention.

Claim 1 has been amended to recite specific saposins which correlate with specific lysosomal storage disorders (LSDs). This amendment finds support throughout the specification, and in Table 1.

Claim 5 has been amended for clarity in light of the amendments to Claim 1.

Claim 18 has been cancelled.

Claim 36 has been amended to remove reference to urine or amniotic fluid and to recite specific saposins which correlate with specific LSDs. This amendment finds support throughout the specification, and in Table 1.

Claim 39 has been amended to recite specific saposins which correlate with specific LSDs. This amendment finds support throughout the specification, and in Table 1.

## **CLAIM REJECTIONS – 35 USC §112, ENABLEMENT**

1. Claim 36 stands rejected under 35 USC §112, first paragraph, on the grounds that it is not enabled by the Specification. The Examiner has stated that the Specification of the current application supports practicing the invention in plasma, serum, and whole blood sample. However, the Examiner is of the opinion that there is insufficient support for practicing the invention in urine or amniotic fluid. The Examiner asserts that there is no disclosure in the Specification that the levels of saposins were measured in urine or amniotic fluid samples.

In response, Applicants have amended Claim 36 to remove references to urine or amniotic fluid samples. Applicants submit that these amendments cause Claim 36 to be in condition for allowance.

2. Claims 1, 4-6, 8-12, 15-17, 19-20, 36 and 39 have been rejected under 35 USC §112, first paragraph, on the grounds that the Specification, while being enabling for diagnosing or monitoring certain diseases by correlating with a certain type of saposin, does not reasonably provide enablement for diagnosing or the genus of lysosomal storage disorders.

In response, Applicants have amended Claims 1, 36 and 39 to refer to specific saposins correlating with specific LSDs, as described in Table 1 of the Specification. Applicants submit that these claims, as amended, describe the specific saposins which one of skill in the art would use to monitor or diagnose a specific LSD, and that these claims and their dependent claims are therefore enabled by the Specification.

Applicants therefore respectfully submit that Claim 1, as amended, and dependent claims 4-6, 8-12, 15-17, 19-20, as well as Claims 36 and 39, meet the enablement requirement of 35 USC §112, first paragraph, and are in condition for allowance.

#### **CLAIM REJECTIONS – 35 USC §112, ENABLEMENT**

1. The Examiner has also rejected Claim 36 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that there is insufficient demonstration that the level of saposins in urine or amniotic fluid would correlate with the diagnosis of any of the many types of lysosomal storage disorder.

Applicants respectfully submit that the amendment to Claim 36 described above removes reference to urine and amniotic fluid, thereby removing the basis for this rejection. Claim 36 is therefore in condition for allowance.

2. Claims 1, 4-6, 8-12, 15-17, 19-20, 36, and 39 stand rejected under 35 USC §112, first paragraph on the grounds that they do not comply with the written description requirement.

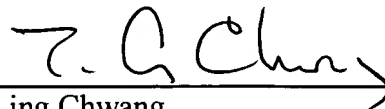
The Examiner states that these claims contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time the application was filed since there may be a strong correlation between the level of saposin and one type of lysosomal storage disorder without a strong correlation between the level of saposins and another type of lysosomal storage disorder.

Applicants submit that Claims 1, 36, and 39, as amended, recite a method for correlating a specific saposin with a specific LSD, and therefore that the inventor was in possession of the claim material at the time the application was filed. Similarly, dependent claims 4-6, 8-12, 15-17, 19-20, satisfy the written description requirement. Applicants therefore respectfully submit that Claims 1, 4-6, 8-12, 15-17, 19-20, 36, and 39, are in condition for allowance.

### **CONCLUSIONS**

Applicants respectfully submit that, in light of the foregoing amendments and comments, Claims 1, 4-6, 8-12, 15-17, 19-20, 36, and 39 are all in condition for allowance. A Notice of Allowance is therefore requested for all claims. If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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Dec. 7, 2007